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ONE HUNDRED SIXTH CONGRESS

# Congress of the United States

## House of Representatives

COMMITTEE ON GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

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MINORITY (202) 225-5051  
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August 9, 2000

HENRY A. WAXMAN, CALIFORNIA,  
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INDEPENDENT

The Honorable Donna E. Shalala, MD  
Secretary of Health and Human Services  
Department of Health and Human Services  
200 Independence Avenue, South  
Washington, DC 20201

Dear Dr. Shalala:

On May 16, I wrote to you to ask you to assemble a panel of experts to review the existing scientific research into a possible link between the MMR vaccine and autism. I understand that you received a similar letter from Congressman Waxman around the same time.

Our letters followed a Government Reform Committee hearing that explored the dramatic increase in cases of autism over the last several years. A panel of parents gave emotional testimony about their children, who developed acquired autism shortly after receiving their MMR booster shots. We also heard testimony from two British researchers. One testified that the findings of his research were consistent with a link between the MMR vaccine and autism. The other testified that his findings were not consistent with such a link.

In my letter, I asked you to assemble a panel of pre-eminent scientific experts, who are free of financial conflicts of interest, to do the following:

- (1) Evaluate the existing literature and research regarding autism, vaccines, and any possible adverse event that could lead to the onset of autism;
- (2) Determine if there is enough existing science to make a clear determination about a possible link between autism and vaccines;
- (3) Provide a systematic evaluation to the quality of the existing body of research; and
- (4) Provide recommendations regarding the research that would be needed to conclusively determine whether or not any vaccines can be linked to the onset of autism.

I also made the following requests:

- (1) That the names, resumes, and financial disclosure forms of the proposed panel members be submitted to the Government Reform Committee in advance of the formalization of the panel;
- (2) That the implementation plan and timeline be submitted to the Committee by May 31;

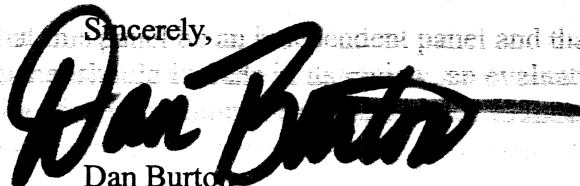
- (3) That a full report to the Government Reform Committee on the findings of this panel be submitted at the conclusion of the panel's investigation;
- (4) That interim reports should be provided by December 31, 2000, and June 30, 2001, if the panel's work is not complete; and
- (5) That monthly updates on the progress of the development of this panel and its work be provided to the Committee.

Today is August 9. I am deeply disappointed that I have not received even a preliminary reply from you in more than two-and-a-half months. About one month ago, my staff inquired about this matter with your staff. My staff was informed that you had not received my letter, although it was faxed and mailed to you. The letter was retransmitted. And yet, one month later, I have still received no response.

This is a very important issue. Parents across the country are concerned about the possible side effects of this vaccine. These questions cannot be ignored. They must be resolved one way or the other. It is insufficient for the FDA and the CDC to simply state that there is no research to support a connection between the MMR vaccine and autism if no research has been done and nobody is prepared to do any.

I am attaching a copy of my original letter. Please give this matter your personal attention. If I do not receive a response, I will schedule a hearing, and issue subpoenas if necessary, so that we can discuss this matter in public session. If you have any questions, please have your staff contact Professional Staff Member S. Elizabeth Clay at 202-226-5867.

Sincerely,



Dan Burton  
Chairman

Enclosure

cc:

The Honorable Henry Waxman  
Ranking Minority Member

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BERNARD SANDERS, VERMONT  
INDEPENDENT

May 16, 2000

The Honorable Donna Shalala, M.D.  
Secretary of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Madame Secretary:

As you are aware, the Government Reform Committee conducted a hearing on April 6 regarding the dramatic increase in autism rates. On behalf of the Committee, I urge you to convene a panel of experts in autism, neurology, immunology, virology, histopathology, epidemiology and other appropriate disciplines to conduct a comprehensive Cochrane Collaboration style systematic review of the existing state of the science concerning the possibility that childhood immunizations can cause or contribute to the onset of autism.

We ask that this panel be an independent panel and that its members be free of conflicts of interest. This panel should include in its review, an evaluation of the existing literature and research, determine if there is enough existing science to make a clear determination, and provide a systematic evaluation to the quality of the existing body of research. The panel should also provide recommendations regarding research needs. I ask that the names, resumes, and conflict of interest forms of the proposed panel members be submitted to the Government Reform Committee in advance of the formalization.

At the April 6 hearing, testimony was presented by witnesses who postulated this link between childhood immunizations and the onset of autism. Other witnesses disagreed and testified that the scientific evidence does not support such a connection.

Like the witnesses, we also disagree on this issue. I believe that there currently exists evidence, both anecdotal and scientific, to indicate a causal connection between vaccines, their possible adverse effects and acquired autism and that more research needs to be conducted to further understand this issue. Representative Waxman believes that the scientific evidence does not support such a connection.

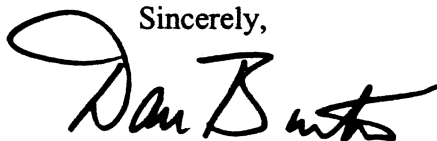
We agree, however, that an expert panel could help resolve these concerns and lay the groundwork for future research. It is important to determine whether or not enough research evidence has been accrued to make such a determination. It is also important to insure that we have a firm foundation in long-term safety studies in vaccines, which according to the Institute of Medicine does not exist. Because of the vital public health importance of childhood immunizations, as well as the growing concerns over the prevalence of autism in the United States, we believe that an expert panel of leading scientists and clinicians who do not have a vested interest in vaccine issues, should review all the available data regarding any possible connections between vaccines and autism.

As part of this work, we request that the expert panel obtain and evaluate the raw data, and where appropriate, tissues samples from the scientific witnesses that testified at the April 6, 2000 hearing.

Please provide an implementation plan and timeline by May 31. A full report to the Government Reform Committee on the findings of this panel is requested at the conclusion of the panel's investigation. An interim reports should be provided by December 31, 2000, and June 30, 2001 if the panel's work is not complete. Please provide monthly updates on the progress of the development of this panel and its progress. If you should have any questions, please have your staff contact Ms. S. Elizabeth Clay at 202-225-5074.

We appreciate your attention to this important public health issue and look forward to your response.

Sincerely,

A handwritten signature in black ink, appearing to read "Dan Burton". The signature is fluid and cursive, with a large initial "D" and a stylized "B".

Dan Burton  
Chairman